

Magnesium sulphate for the prevention of supra-ventricular dysrhythmia following non-cardiac thoracic surgery

Submission date 11/06/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/08/2013	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Roger Stedman

Contact details

2nd Floor
Lincoln House
Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B5 5SS

Additional identifiers

Clinical Trials Information System (CTIS)

2004-002818-11

Protocol serial number

Version 5

Study information

Scientific Title

Acronym

MAGNETS

Study objectives

The prophylactic perioperative correction of magnesium deficiency by infusion of magnesium sulphate to all patients presenting for thoracotomy or thoracotomy for pneumonectomy, lobectomy or oesophagectomy will significantly reduce the incidence of supra-ventricular dysrhythmias post operatively.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Birmingham Research Ethics Committee. Date of approval: 04/05/2005 (ref: 05/Q2707/1)

Study design

Single-centre prospective double-blind randomised placebo-controlled study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Supra-ventricular dysrhythmias in patients following non-cardiac thoracic surgery

Interventions

Patients are randomised into either the placebo or magnesium groups. Patients receive either placebo or 5 g magnesium sulphate infusion intra-operatively, day 1 and day 2 post-operatively. Continuous electrocardiogram (ECG) recording for 5 days will be commenced using a holter (non-invasive) recorder after induction of anaesthesia. ECG data will be analysed by a cardiac physiologist who is blinded from which treatment group the patient is in.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Magnesium sulphate

Primary outcome(s)

To demonstrate a clinically and statistically significant reduction in the incidence of postoperative supra-ventricular dysrhythmias in the patient group who have received magnesium in comparison to the placebo group. It is aimed that patients have holter monitoring for 5 days post-operatively.

Key secondary outcome(s))

1. Length of hospital stay
2. Thirty-day mortality

Completion date

30/06/2008

Eligibility**Key inclusion criteria**

1. Both male and female patients
2. Above 18 years; no upper age limit
3. Patients presenting to the Department of Thoracic Surgery at Birmingham Heartlands Hospital for elective lobectomy, bi-lobectomy, pneumonectomy or oesophagectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Evidence of renal failure (serum creatinine of >130)
2. Liver failure
3. Pre-existing cardiac arrhythmia
4. Undergoing long-term treatment for an arrhythmia
5. On long-term treatment with nifedipine or aminoglycosides
6. Known hypersensitivity to magnesium sulphate
7. If preoperative magnesium level is equal or greater than 1.2 mmol/l
8. If they are unwilling or unable to give informed consent for their participation or if they withdraw consent
9. Patients who have participated in another interventional study within the previous 3 months

Date of first enrolment

01/06/2006

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

2nd Floor

Birmingham

United Kingdom

B5 5SS

Sponsor information

Organisation

Heart of England NHS Foundation Trust (UK)

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (UK)

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

European Association of Cardiothoracic Anaesthesiologists (EACTA) (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2011		Yes	No